

**DRAFT FOR WORKGROUP REVIEW (BASED UPON DISCUSSION OF  
FEBRUARY 26, 2008 MEETING).**

**MRT Workgroup Report  
And Proposed Language by the MRT Workgroup  
FOR PROTON BEAM THERAPY  
By Dr. Marc Keshishian, Chair, MRT Workgroup**

Please reference the CON Megavoltage Radiation Therapy (MRT) Standards at the following link in order to reference the sections noted below under Section 9A(2) that are being excluded for proton beam therapy:

[http://www.michigan.gov/documents/mdch/MRT\\_Standards\\_204886\\_7.pdf](http://www.michigan.gov/documents/mdch/MRT_Standards_204886_7.pdf)

**(ADDITION TO) Section 2. Definitions**

(K) "CYCLOTRON" MEANS, FOR PURPOSES OF SECTION 9A, A PARTICLE ACCELERATOR IN WHICH HYDROGEN PARTICLES ARE ACCELERATED AND PROTONS ARE EXTRACTED TO CREATE A PROTON BEAM.

(WW) "PROTON BEAM THERAPY" OR "PBT" MEANS A TYPE OF PARTICLE THERAPY THAT UTILIZES A CYCLOTRON TO ACCELERATE PROTONS, SENDING THEM THROUGH A BEAM TRANSPORT SYSTEM TO INDIVIDUAL TREATMENT ROOM(S), WHERE THEY ARE USED TO IRRADIATE A TUMOR SITE IN THE TREATMENT OF CANCER.

**(NEW) SECTION 9A. REQUIREMENTS FOR APPROVAL – APPLICANTS PROPOSING TO INITIATE AN MRT SERVICE PROVIDING PROTON BEAM THERAPY**

SEC. 9A. (1) AN APPLICANT PROPOSING TO INITIATE AN MRT SERVICE PROVIDING PROTON BEAM THERAPY SHALL DEMONSTRATE THAT IT MEETS ALL OF THE FOLLOWING AT THE TIME THE APPLICATION IS SUBMITTED TO THE DEPARTMENT:

(A) AN APPLICANT SHALL BE A SINGLE LEGAL ENTITY AUTHORIZED TO DO BUSINESS IN MICHIGAN.

(B) AN APPLICANT SHALL BE A STATEWIDE COLLABORATIVE THAT CONSISTS OF

(I) AT MINIMUM, ALL MICHIGAN MRT HOSPITAL SERVICES WITH MORE THAN 30,000 ETVS, AND

(II) THE HIGHEST VOLUME MRT HOSPITAL SERVICE IN PLANNING AREAS NOT ALREADY REPRESENTED BY THOSE MRT SERVICES OPERATING AT MORE THAN 30,000 ETVS SO THAT THE APPLICANT SHALL INCLUDE AT LEAST FOUR OF THE EIGHT MICHIGAN PLANNING AREAS IN THE COLLABORATIVE.

(C) FOR THE PURPOSES OF THIS SECTION, ETVS SHALL BE THOSE FROM THE MOST RECENT DATA AVAILABLE TO THE DEPARTMENT AT THE TIME THE APPLICATION IS SUBMITTED.

(D) AN APPLICANT SHALL PROVIDE DOCUMENTATION OF ITS PROCESS, POLICY AND PROCEDURES THAT WILL ALLOW ANY OTHER INTERESTED ENTITIES TO PARTICIPATE IN THE STATEWIDE COLLABORATIVE AND THE PBT SERVICES IT OFFERS.

(E) AN APPLICANT SHALL PROVIDE AN IMPLEMENTATION PLAN FOR FINANCING AND OPERATING THE PROPOSED PBT SERVICE INCLUDING, BUT NOT LIMITED TO, HOW PHYSICIAN STAFF PRIVILEGES, PATIENT REVIEW, PATIENT SELECTION, AND PATIENT CARE MANAGEMENT SHALL BE DETERMINED.

(F) AN APPLICANT SHALL INDICATE THAT PBT SERVICES WILL BE PROVIDED TO BOTH ADULT AND PEDIATRIC PATIENTS.

(G) AN APPLICANT SHALL DEMONSTRATE THAT THE PBT SERVICE WILL HAVE SIMULATION CAPABILITIES AVAILABLE FOR USE IN TREATMENT PLANNING.

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(H) AN APPLICANT SHALL DEMONSTRATE THAT THE FOLLOWING STAFF, AT A MINIMUM, WILL BE PROVIDED:

- (I) 1 FTE BOARD-CERTIFIED OR BOARD-QUALIFIED PHYSICIAN TRAINED IN RADIATION ONCOLOGY,
- (II) 1 BOARD-CERTIFIED OR BOARD-QUALIFIED RADIATION PHYSICIST CERTIFIED IN THERAPEUTIC RADIOLOGIC PHYSICS,
- (III) 1 DOSIMETRIST OR PHYSICS ASSISTANT,
- (IV) 2 RADIATION THERAPY TECHNOLOGISTS [REGISTERED OR ELIGIBLE BY THE AMERICAN REGISTRY OF RADIOLOGICAL TECHNOLOGISTS (AART)], AND
- (V) 1 PROGRAM DIRECTOR WHO IS A BOARD-CERTIFIED PHYSICIAN TRAINED IN RADIATION ONCOLOGY WHO MAY ALSO BE THE PHYSICIAN REQUIRED UNDER SUBSECTION (I)(I).

(2) AN APPLICANT PROPOSING TO INITIATE AN MRT SERVICE PROVIDING PROTON BEAM THERAPY SHALL BE EXEMPT FROM MEETING THE REQUIREMENTS OF SECTIONS 4 (Initiation of other than PBT); 5 (Expansion); 6 (Replace/upgrade); 8 (Acquisition); 9 (Relocation); 15(1)(C)(I), (II)(B), (VI), (IX) 15(2)(A), AND (B) OF THE PROJECT DELIVERY REQUIREMENTS IN THE STANDARDS.

**(ADDITION TO) Section 15. Project delivery requirements terms of approval for all applicants**

**(2A)** AN APPLICANT FOR AN MRT SERVICE PROVIDING PROTON BEAM THERAPY UNDER SECTION **9A** SHALL AGREE THAT THE PBT SERVICE APPROVED PURSUANT TO SECTION **9A** SHALL BE DELIVERED IN COMPLIANCE WITH THE FOLLOWING TERMS OF CON APPROVAL:

(A) ALL PATIENTS TREATED AT THE APPROVED PBT SERVICE SHALL BE EVALUATED FOR POTENTIAL ENROLLMENT IN RESEARCH STUDIES FOCUSING ON THE APPLICABILITY AND EFFICACY OF USING PROTON BEAM THERAPY TO TREAT SITE SPECIFIC CANCER TUMORS. THESE REPORTS SHALL BE SHARED WITH THE CON COMMISSION.

(B) THE PBT SERVICE SHALL PROVIDE THE CON COMMISSION, ON AN ANNUAL BASIS, WITH REPORTS DESIGNED TO ASSESS THE AFFORDABILITY, QUALITY, AND ACCESSIBILITY OF PBT SERVICES IN MICHIGAN.

(C) AN APPLICANT SHALL BE REQUIRED TO REPORT TO THE DEPARTMENT, ON AN ANNUAL BASIS, VOLUME RELATED DATA FOR ITS PBT UNIT.

(D) THE APPLICANT SHALL BE REQUIRED TO MEET THE MINIMUM VOLUME REQUIREMENTS ESTABLISHED BY THE CON COMMISSION IN ANY SUBSEQUENT REVISION OF THE CON STANDARDS FOR PROTON BEAM THERAPY SERVICE.